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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/723,697 | 11/26/2003 | Marilyn V. Zager | TLR-5130 US | 7836 |

7590 07/28/2005

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| EXAMINER | |
|---|---|
| LEITH, PATRICIA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,697 | ZAGER, MARILYN V. | |
| | Examiner | Art Unit | |
| | Patricia Leith | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



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## DETAILED ACTION

Claims 1-16 are pending in the application.

### *Election/Restrictions*

Applicant's election of Group I, claims 1-15 and the species of glycerin in the reply filed on 4/28/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 16 is hereby withdrawn from consideration on the merits as it is directed toward a non-elected invention.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holt (US 5,869,533).**

Holt (US 5,869,533) disclosed a composition comprising capsaicin (a capsaicinoid) along with carriers such as glycerine and polyethylene glycol (see claims 1-7). Holt did not specifically teach wherein the carrier was found in the composition at the specified parts by volume as required by claim 1.

However, Holt did specifically teach that "Even trace concentrations of capsaicin (such as 0.00001% by weight) will provide a minute therapeutic effect" and that concentrations greater than 1% have a burning effect (see col.3, lines 31-34 and claim 2).

One of ordinary skill in the art would have been motivated to prepare a topical composition with the claimed ratio of capsaicin to carrier in order to impart a warming effect without burning. It is clear from Holt that concentrations as low as 0.00001% have therapeutic value.

**Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791 B1).**

Lezdey et al. (US 6,428,791 B1) taught a topical lubricating composition for enhancing sexual performance comprising capsaicinoids, primrose oil and carriers such as propylene glycol (see Example 4 and claims 1-4).

Lezdey et al. did not specifically teach the ratio of an organic fluid carrier to the capsaicin.

Although Lezdey et al. did not specifically teach the ratio of an organic fluid carrier to the capsaicin, It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of capsaicin because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. One of ordinary skill in the art would have been motivated to adjust the concentration of capsaicin in order to moderate/vary the degree of heat associated with the product; i.e., mildly hot –vs- extra hot.

**Claims 4, 5, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791 B1) as applied to claims 1-2 above, and further in view of Nicolicchia (US 5,770,206).**

The teachings of Lezdey et al. were discussed *supra*. Lezdey et al. did not disclose wherein honey or a colorant was added into the composition.

Nicolicchia (US 5,770,206) taught a body oil for use as a 'sexual stimulant' which comprised paprika for color and honey for taste (see col. 2, lines 10-16).

One of ordinary skill in the art would have been motivated to add honey to the composition disclosed by Lezdey et al. in order to impart a palatable taste to the composition. Further, one of ordinary skill in the art would have been motivated to add a colorant to the composition disclosed by Lezdey et al. in order to impart color to the composition. The addition of these materials were common in the practice of making sexual lubricants/ body oils and would make the product more attractive to consumers.

**Claims 6, 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791 B1) in view of Nicolicchia (US 5,770,206) as applied to claims 4, 5, 8 and 10 above, and further in view of Voss et al. (US 4,801,587).**

The teachings of Lezdey et al. and Nicolicchia were discussed *supra.* Neither reference specifically taught wherein their compositions contained glycerin as the carrier.

Voss et al. (US 4,801,587) taught that glycerin was a conventionally used carrier in topically applied compositions for treatment of impotence (see col. 3, lines 42-50).

One of ordinary skill in the art would have been motivated to substitute the propylene glycol disclosed by Lezdey et al. with glycerin, as glycerin would have acted as a functional equivalent to propylene glycol in lubricating capacity especially lacking any evidence to the contrary, and lacking any unexpected results.

Although none of the references taught the concentrations of ingredients as found in claim 12, again, concentration is a result-effective variable; wherein finding optimal ranges is considered routine in the art of pharmacology.

**Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791 B1) in view of Nicolicchia (US 5,770,206) in view of Voss et al. (US 4,801,587) as applied to claims 6, 9, 12 and 13 above, and further in view of Geria et al. (US 4,780,309).**

The teachings of Lezdey et al., Nicoliccha and Voss et al. were described *supra*. None of these references specifically suggested the incorporation of a vanilla extract in order to impart an odor to the composition.

Geria et al. (US 4,780,309) disclosed a palatable aerosol oil containing foam comprising vanillin (an extract of vanilla) (see Example 1).

One of ordinary skill in the art would have been motivated to add vanillin to the composition in order to impart a favorable odor thereby rendering the composition more attractive to the consumer.

It is clear from the prior art references that the addition of carriers/colorants/flavorants were routine in the art. It would not have required a substantial inventive contribution in order to impart known, conventional carriers, colorants and flavorants to the composition, as addition of these additives were, again, typically added to topical formulations.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

07/20/05